DISCUSSION PAPER

TECHNICAL ISSUES RELATING TO PROVISION OF DATA TO NICNAS BY INDUSTRY WITHIN THE AICS PRIORITISATION PROJECT

PURPOSE OF THE WORKSHOP ON EXPOSURE DATA FOR PRIORITISATION

NICNAS is undertaking a project (the "Prioritisation Project") which will prioritise for further assessment all of the chemicals on the Australian Inventory of Chemical Substances (AICS). The priority for each chemical will be based on risk to humans and the environment, rather than hazard alone. This means that information on the use of each chemical and the amount in use in Australia ("Exposure Data") will be important for determining the priority.

The Exposure Data workshop is intended to explore the issues associated with provision of exposure data by industry. NICNAS is seeking your ideas and suggestions to facilitate this process. Information gained at the workshop will be used to develop a framework for collecting the data needed for prioritisation. To this end, the workshop will address the specific questions under "Issues for Consideration at the Workshop", below.

BACKGROUND ON THE NICNAS AICS PRIORITISATION PROJECT

The final report of the NICNAS Existing Chemicals Program Review (December 2006) proposed that NICNAS undertake the screening of all chemicals listed on AICS according to both hazard and risk indicators, so that those chemicals posing the greatest concern could be identified as priorities for further assessment, while still providing more limited information on the remaining chemicals. "Hazard indicators" refers to information on intrinsic toxicity of the chemical to humans and the environment, while "risk indicators" includes both the hazard and the likelihood that the public, workers or the environment would be affected by the chemical ("exposure").

Planning for the Prioritisation Project involves ongoing consultation with several steering committees containing representatives of industry, Government and the community. AICS includes approximately 38000 chemicals, and so it is clear that the project is a major undertaking.

In preparation for this project, NICNAS has examined the availability of experimental data on toxicity for a representative sample of the chemicals on AICS, and have found that a high proportion of the chemicals on AICS have extremely limited or no data. Use of electronic prediction methods such as QSAR will only partly address these data gaps, as many of the chemicals on AICS are likely to be outside the range of chemical structures for which good predictions can be made. Therefore, the objective of developing a prioritised list of chemicals for further assessment cannot be achieved on the basis of toxicity information alone.

Canada has already completed a similar screening exercise on the 23000 chemicals comprising its Domestic Substances List (DSL; equivalent to AICS). Canada's prioritisation program used information on the amount of the chemical imported or manufactured, and the uses to which it was put, as critical components of priority determination, particularly for human health. However, when Canada undertook screening of the DSL, this information was available for all chemicals as it formed part of the data collection at the time the DSL was

compiled. In contrast, equivalent information on the quantities introduced and the uses was not collected at the time of AICS compilation, prior to the establishment of NICNAS in 1991.

The approaches used by Canada largely form the basis of the Australian Prioritisation Project, but there are a number of reasons why the results of the Canadian screening will make only a limited contribution to the Prioritisation Project.

A major aim is to identify chemicals that may not be in use in Australia, or used only in small quantities, so that resources can be focussed on the chemicals with a higher level and/or breadth of exposure.

ISSUES FOR CONSIDERATION AT THE WORKSHOP

AICS contains a large number of chemicals, and the majority of these chemicals lack toxicological data. Except in the rare cases where a chemical can easily be demonstrated to be of extremely low hazard, it is necessary to use information on the number of people who may come into contact with the chemical and the amount of the chemical that each person may come into contact with ("exposure data") to determine the risk based priority for the chemical.

It is possible to use models to determine the exposures, but these rely on the availability of accurate information on:
  - How much of the chemical is in use in Australia ("quantity introduced"); and
  - What use (or uses) the chemical is put to ("use").

This information would be required from each company manufacturing and/or importing ("introducing") the chemical.

To complete the prioritisation of individual chemicals, NICNAS will, in many cases, need both these pieces of information. However, for a proportion of chemicals on AICS, the amount of chemical being used in Australia will be sufficiently small such that the priority for further assessment may be considered low for this reason alone, regardless of the specific use of the chemical. In addition, for other chemicals, where the hazard is determined to be low, these may also be determined to be of low priority, regardless of use and quantity introduced.

This leads to three exposure information items which will need to be obtained from industry:
  a) The identity of chemicals manufactured and/or imported by the company in Australia;
  b) The quantity of each chemical which is introduced, including in products and mixtures; and
  c) The uses of the chemical and any products it is contained in.

NICNAS would like to collect the necessary information with minimum impact on industry. Discussion of the following issues will be important in achieving this.

Availability of Exposure Information

The availability of these information items from each individual company will depend on the type of system used within the company for managing the inventory of chemicals that it imports and/or manufactures. Understanding the data availability is therefore a major issue for NICNAS in developing a framework for data collection.

In addition to these questions, more detailed issues such as practicalities of providing information and preferred formats will be discussed at the Workshop.

Options for Data Collection
To collect the information identified above, there are two potential mechanisms that could be used:
- Publishing lists of chemicals and asking industry to provide the requested information on the chemicals on the list that they introduce; or
- Asking each company to provide the requested information on all industrial chemicals that they introduce.

In either case, the treatment of confidential and third party information needs to be considered.

If the first option is used, and given the number of chemicals on AICS, there are likely to be a number of long lists of chemicals.

A two phase approach could also be used. The first phase could collect information on which chemicals are imported and/or manufactured in Australia and the quantity introduced. In phase 2, information on the use of the chemical could be requested only from those companies that have indicated that they are using that chemical.

Threshold Quantity
Every company manufacturing and/or importing a chemical will hold information of value in prioritising the chemical. However the risk posed by a chemical is in part dependent on the amount of the chemical used in Australia. Therefore, to minimise the impact of the information collection on industry, and particularly small business, it is possible that a threshold quantity can be set below which any chemical does not need to be reported as part of prioritisation.

It should be noted that the threshold quantity needs to take into account toxicological considerations and community concerns.

Reporting Period

NICNAS understands that the manufacture and/or import of individual chemicals may be irregular. Therefore, asking for data on the chemicals introduced in a single year may not give an accurate picture of the chemicals in use in Australia. NICNAS is seeking advice about the most representative time period for which the information should be requested, in order to accurately represent all chemicals in use in Australia. In addition, NICNAS would like to determine whether this period should be retrospective, prospective, or a mixture of the two. This depends in part on whether the appropriate retrospective data is available within companies.

For purposes of maximising the cost efficiency for NICNAS, retrospective data would be particularly useful, as this would allow the project to proceed more quickly.